INEEL[a] QUALITY ASSURANCE PROGRAM REQUIREMENTS DOCUMENT

1. PURPOSE

The Quality Assurance (QA) Program Requirements Documents (PRDs) in this manual establish requirements and broad-scoped responsibilities for the Idaho National Engineering and Environmental Laboratory (INEEL) QA program. The PRDs are used by performing organizations to identify and incorporate applicable QA requirements into their operations, program/project-specific planning, and procedures.

2. APPLICABILITY

The INEEL QA program includes all work performed by Bechtel BWXT Idaho, LLC (BBWI) i.e., engineering, operations, maintenance and repair, construction, research and development, safeguards and security, administration, software development, data collection and analysis, environmental restoration, etc.

The QA PRDs identify the requirements that apply to the company-at-large, and those that are limited to DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description. The PRDs are aligned with the requirements of ANSI/ISO 14001, Environmental Management Systems-Specification with Guidance for Use. The PRDs also apply to *work for others* (see def.) unless the work for others agreement has established alternative QA program requirements.

The QA PRDs do not apply to NRC licensed facilities or Waste Isolation Pilot Program activities. They are controlled by QA plans separate from the QA PRDs.

3. RESPONSIBILITIES

The quality assurance organization is responsible for establishing and revising QA PRDs.

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[a] The term INEEL applies solely to the BBWI scope of operations; it does not apply to other INEEL companies or organizations. INEEL is used in this context throughout the PRDs.

4. REQUIREMENTS AND QUALITY PROGRAM IMPLEMENTATION

4.1 QA Program Description

Policy. The company quality policy commits BBWI to produce the highest quality products and services and meet customer expectations through a program of continuous improvement. To achieve this policy, BBWI institutes and maintains an effective QA program that integrates with and supports the Integrated Safety Management System (ISMS). The QA program promotes the achievement of quality through (a) planning and documenting requirements for items, processes, and services; (b) controlling activities affecting the quality of those items, processes, and services; (c) verifying the achievement of required quality; (d) analyzing and correcting conditions adverse to quality in a continuing process of self-improvement.

Responsibility for Quality. The INEEL quality assurance program is a shared interdisciplinary function as shown in PRD-5070, 1.1 Organization, PRD-5071, 2.1 Quality Assurance Program, and the balance of the PRDs.

Management is responsible for the quality of the work that their organizations perform, and for ensuring compliance with all procedures that govern the work. Each individual is responsible for the quality of his or her work and following work instructions. It is the worker's responsibility to stop work when an activity presents unsafe conditions or a significant condition adverse to quality.

Graded Approach. The quality assurance program uses the *graded approach* (see def.) to establish the level of rigor that should be applied in performing work. Gradation is written into implementing documents as appropriate. The graded application of the QA requirements is consistent with the safety impact of an activity, a process, or an item on the workers, the public, and the environment.

Quality Training. Management ensures, through a formal, documented indoctrination and training program, that personnel understand the basic QA program. Additional in-depth training is provided as appropriate to meet facility-specific and job-related needs.

Feedback and Continuous Improvement. QA program implementation is verified through a two-tiered field assessment program. The first tier consists of on-going individual facility and programmatic self-assessments. These are performed by appropriate facilities and organizations to determine the level of compliance, promote continuous improvement, and enhance performance. The second tier consists of independent audits performed by organizations or individuals who have not participated in or are responsible for the work being evaluated.

4.2 Quality Plans and Quality Implementing Procedures

The QA program includes QA requirements, plans, implementing procedures, and other documents. The QA requirements flow down through procedures to management and the workers performing work.

Additional QA plans may be required and developed for specific programs and projects. Quality Program Plans (QPPs) are written whenever there is a need to address unique customer requirements that are not reflected in the company's base program, or to authorize a deviation for a specific program or project. Quality Assurance Project Plans (QAPjPs) are written to address how Environmental Protection Agency requirements are applied to company operations.

Managers establish procedures that comply with the requirements of the QA PRDs, and ensure procedures are followed by those performing the work. Instruction for how to implement the quality program requirements are placed in implementing documents. (See LST-200, QA Program Implementing Document Reference List, in this manual for a list of companywide documents.)

Implementing procedures address all the organizational interfaces that are necessary to control work. Work performed under the QA program is done to approved instructions and procedures by qualified people. Each individual is responsible for following the requirements of applicable procedures/instructions. Employees are to comply with the procedures as written. If following a procedure presents an unsafe condition, work is stopped as soon as it is safe to do so and resolution is achieved. Work may be resumed only when the procedure has been changed in accordance with appropriate procedures to reflect safe and correct work practices. Similarly, *conditions adverse to quality* (see def.) are also evaluated and work is stopped as necessary until the problem is resolved.

4.3 QA PRD Use

The QA PRD sections represent quality program topics described in NQA-1, plus a section on the management of environmental data. Plan and procedure owners use the QA PRD to develop or revise QPPs, QAPjPs, or implementing procedures. The plan or procedure owner ensures the document being developed or revised meets the appropriate QA requirements. The QA PRD requirements are documented in procedure basis documents to show the flowdown.

Document owners determine which QPPs, QAPjPs, and implementing procedures are affected when a source document requirement is revised. When new (or revised) requirements are invoked, the document owner evaluates current documents and revises them accordingly. When a procedure is revised, a document owner verifies that the revision does not negate or modify requirement implementation.

4.4 QA PRD Format

Each PRD contains sections that define its purpose, applicability, the responsibilities of management and personnel, quality assurance requirements and how they apply, and any special implementing requirements established by management for effective implementation of requirements.

Each section of the manual identifies the sources of the requirements traceable to a specific citation. In the main body of the PRDs, the source of each requirement is identified by a citation enclosed in brackets at the end of each statement or series of statements. Each PRD also contains an appendix which provides a complete listing of requirements found in the PRD.

The majority of the requirements contained herein are from NQA-1 Part I and Subpart 2.7; and DOE/RW-0333P excluding Supplements II and III and Appendices A and C. The requirements are established such that restatements of similar NQA-1 and DOE/RW-0333P or requirements from other sources do not occur. NQA-1 and DOE/RW-0333P requirements are listed as consensus requirements in each PRD to form the foundation for the companywide QA program. DOE/RW-0333P requirements are contained in this foundation if they are within the spirit and intent of NQA-1. Company self-imposed requirements that reflect good business practice are also included.

DOE/RW-0333P or other requirements that are more restrictive than NQA-1 and take additional resources to implement are placed in their own subsection. These are identified as requirements specific to activities that must meet all DOE/RW-0333P requirements.

Acronyms used in the QA PRDs are explained in LST-198, Acronyms. Terms that are defined are italicized and flagged as defined terms in the QA PRD text. The definitions are provided in LST-199, Definitions. A listing of the company-level procedures used to implement the QA program is provided in LST-200, QA Program Implementing Document Reference List. LST-198, LST-199 and LST-200 are located in the back of this manual.

5. DEFINITIONS

Refer to LST-199, Definitions, in the QA PRD manual for the definitions of the following terms:

condition adverse to quality

graded approach

work for others

6. REFERENCES

10 CFR 830, Subpart A, Quality Assurance Requirements

48 CFR, Chapter 1, Part 46, Quality Assurance

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

ANSI/ISO 14001-1996, Environmental Management Systems-Specification with Guidance for Use

DOE Order 414.1A, Quality Assurance, September 1999

DOE Order 440.1A, Worker Protection Management for DOE Federal and Contractor Employees, March 1998

DOE-ID O 414.A, Quality Assurance, May 2000

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

7. APPENDICES

None